

Remarks

A. Status of the Claims

Claim 1-9, 11-14, 16-20, 26-32, 36- 37, and 146-150 are pending. Claim 146 has been amended to correct a typographical error.

B. The Claims are Novel Over Xu

The Action rejects claims 1-9, 11-14, 16-19, 26, 36, 37, and 146-150 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,496,731 to Xu *et al.* as evidenced by U.S. Patent No. 6,590,086 to Fung *et al.* and Donehower *et al.* (The Cancer Bulletin 46:161-166 (1994)). Applicant traverses this rejection.

The Action fails to establish a *prima facie* case of anticipation because Xu does not teach all of the limitations of the current claims. Xu is concerned with “a broad-spectrum tumor suppressor gene and the protein expressed by that gene,” which Xu describes as a *retinoblastoma protein of about 94 kD* (Xu, Abstract). Accordingly, the treatments contemplated by Xu are described as using a *p94^{RB} expression vector or p94^{RB} protein* (Xu, Abstract). While the Action notes that section 1.3.3.3 in the Background of the Xu patent teaches that p53 is a tumor suppressor gene, the Action does not identify any disclosure by Xu that teaches all of the limitations of the current claims. With regard to the treatment of tumor cells using p53, Xu’s section 1.3.3.3 states: “Tumor cell lines deleted for p53 have been successfully treated with wild-type p53 vector to reduce tumorigenicity. However, *the introduction of either p53 or RB¹¹⁰ into cells that have not undergone lesions at these loci does not affect cell proliferation.*” (Xu, col. 5, ln. 21-26) (emphasis added; citations omitted). This does not teach a method of inhibiting growth of or inducing apoptosis in a tumor cell expressing *wild-type p53*. In fact, it teaches away from such an approach.

The Action also states that at column 11, lines 30-33, Xu teaches an embodiment in which the tumor or cancer cells are cells having no detectable genetic defect of a tumor suppressor gene selected from the group consisting of an RB gene and a p53 gene. However, this statement is made in the context of treatment with *p94^{RB}* and not p53 (*see* Xu, Summary of the Invention). As mentioned above, Xu teaches that the introduction of either p53 or RB¹¹⁰ into cells that have not undergone lesions at these loci does not affect cell proliferation.

In view of the above, the claims are novel over Xu. Applicant, therefore, requests the withdrawal of this rejection.

C. The Claims are Patentable Over Xu in View of Fung and Roth

The Action rejects claims 1, 20, 27, and 28-32 under 35 U.S.C. § 103(a) as being unpatentable over Xu (discussed above) in view of U.S. Patent No. 6,590,086 to Fung *et al.* and U.S. Patent No. 6,797,702 to Roth *et al.* Applicant traverses this rejection.

The Action relies on Xu as teaching or suggesting all of the limitations of claim 1. As discussed above, however, Xu does not teach or suggest a method of inhibiting growth of a tumor cell expressing wild-type p53; and in fact, Xu *teaches away* from such an approach. Thus, a *prima facie* case of obviousness has not been established against independent claim 1. If an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. MPEP § 2143.03. Accordingly, the Action also has not established a *prima facie* case of obviousness in regard to claims 20, 27, and 28-32.

Applicant further notes that Roth (U.S. Patent 6,797,702), is not available for establishing the obviousness of the present invention. The Roth patent published on September 28, 2004 and qualifies as prior art only under 35 U.S.C. § 102(e). The present application and Roth were, at the time the invention was made, subject to an obligation of assignment to the Board of Regents

of the University of Texas System. Thus, pursuant to 35 U.S.C. § 103(c), the subject matter disclosed in Zhang cannot preclude the patentability of the claimed invention under § 103.

In view of the above, Applicant requests the withdrawal of this rejection.

D. The Claims are Patentable Over Xu in View of Zhang and Donehower

The Action rejects claims 1-9, 11-14, 16-19, 26, 36, 37, and 146-150 under 35 U.S.C. § 103(a) as being unpatentable over Xu (discussed above) in view of U.S. Patent No. 6,143,290 to Zhang and Donehower *et al.* (The Cancer Bulletin 46:161-166 (1994)). Applicant traverses this rejection.

Again, the Action relies on Xu as teaching or suggesting all of the limitations of independent claim 1. In addition, the Action relies on Xu as teaching or suggesting all of the limitations of independent claim 146. As discussed above, however, Xu does not teach or suggest a method of inhibiting growth of or inducing apoptosis in a tumor cell *expressing wild-type p53*; and in fact, Xu *teaches away* from such an approach. The Action states that Zhang teaches adenovirus expression of wild-type p53 and methods of *restoring* p53 function and tumor suppression in cells having *abnormal* p53. This fails to compensate for the above-mentioned deficiencies in Xu. The Action states that Donehower discloses that it was known that p53 was a mediator of apoptosis. This also fails to compensate for the above-mentioned deficiencies in Xu. Thus, a *prima facie* case of obviousness has not been established against independent claims 1 and 146. If an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. MPEP § 2143.03. Accordingly, the Action also has not established a *prima facie* case of obviousness in regard to any of the claims.

Applicant further notes that Zhang (U.S. Patent 6,143,290), is not available for establishing the obviousness of the present invention. The Zhang patent published on November 7, 2000 and qualifies as prior art only under 35 U.S.C. § 102(e). The present application and

Zhang were, at the time the invention was made, subject to an obligation of assignment to the Board of Regents of the University of Texas System. Thus, pursuant to 35 U.S.C. § 103(c), the subject matter disclosed in Zhang cannot preclude the patentability of the claimed invention under § 103.

In view of the above, Applicant requests the withdrawal of this rejection.

E. The Provisional Double Patenting Rejection

Claims 1-9, 11-14, 16-20, 26-32, 36, 37, and 146-150 are provisionally rejected for non-statutory double patenting over claims 26, 29, 58, and 89 of co-pending Application No. 09/968,958 (the “‘958 application”). The Action asserts that claim 1 of the present application is essentially the same as claims 29 and 58 of the ‘958 application. The Action also asserts that claim 26 of the ‘958 application encompasses essentially the same invention as encompassed by claims 1 and 146 of the present application. Applicant notes that a provisional double-patenting rejection is not a final rejection that blocks the prosecution of all of the conflicting applications. If a provisional double-patenting rejection is the only rejection remaining in an application, the Examiner should withdraw the rejection and permit the application to issue as a patent. *Manual of Patent Examining Procedure*, § 804(I)(B), p. 800-15. After one application issues as a patent, the provisional double-patenting rejection in the remaining application is converted to an actual double patenting rejection. *Id.* Once either the present application or the ‘958 application issues as a patent, Applicant will file a terminal disclaimer, if appropriate, in the remaining pending application.

The Action also indicates that if claim 1 is found to be allowable, claim 146 will be objected to under 37 C.F.R. § 1.75 as being a substantial duplicate thereof. It appears that the Action considers claim 146 as merely reciting a mechanism by which the method of claim 1 works. Applicant notes that such an objection would be improper. As stated in MPEP

§ 706.03(k), “court decisions have confirmed applicant’s right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough.” The scope of the phrases “inhibition of tumor cell growth” and “induction of apoptosis” are not identical.

F. Conclusion

It is respectfully submitted, in light of the above, that all of the pending claims are in condition for allowance. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned attorney at (512) 536-5654.

Respectfully submitted,



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